

## **DETAILED ACTION**

### ***Proposed Examiner's Amendment/Interview Summary***

Applicant's representative, Mr. Lance Termes was contacted with a proposed examiner's amendment to place the application in condition for allowance. Applicants did not submit the proposed amendments in the form of a supplemental amendment as requested. Please refer to accompanying interview summary dated 12/14/10 for further details of the proposed amendments.

### **Status of pending claims**

Claims 398, 402, 403, 410, 414-416 and 424-447 are pending.

Claims 403, 415, 426, 428, 434-436, 443-445, and 447 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/5/09.

Claims 398, 402, 410, 414, 416 424, 425, 427, 429-433, 437-442 and 446 are examined on the merit.

A search for the elected species of the peptide SEQ ID NO: 2 indicated that it is not free of prior art. The art found has been applied in the rejection set forth below.

Any objections and/or rejections made in the previous office action dated 5/19/10 and not specifically discussed below in original or modified form here are considered withdrawn.

## **Maintained Objections/Rejections**

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1654

Claims 398, 402, 410, 414, 416 424, 425, 427 and 429-433, 437-442 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 384-396 of copending Application No. 10/583,464 in view of Shimizu, Journal of Neuroscience Research, 70, 451-461. The rejection has been modified to reflect the amendments to claims filed on 11/30/10.

In the instant invention, applicants claim conjugate comprising a peptide immunogen/polypeptide carrier conjugate wherein the peptide immunogen comprising an A $\beta$  peptide or fragment or analog thereof and wherein the derivatized polypeptide functional group is capped thereby the carrier polypeptide retains the immune response functionality against the peptide conjugate that would otherwise not occur without the carrier.

Claims of copending Application No. 10/583,464 are drawn to peptide immunogen/polypeptide conjugate in general. Claims of copending Application No. 10/583,464 are not drawn to conjugate comprising A $\beta$  peptide as the immunogen peptide.

Shimizu discloses the conjugate of KLH with A $\beta$ 1-12 peptide that comprises the fragment of instantly elected SEQ ID NO:2 (page 452, column 2). Since the conjugate of Shimizu were administered to rabbits, it is pharmaceutically acceptable.

One of ordinary skill in the art would combined the teachings of copending Application No. 10/583,464 and Shimizu to arrive at the instant invention since Shimizu discloses the conjugates of A $\beta$  peptide conjugated to carrier protein KLH. One of ordinary skill the art would have been motivated to do so given the fact that Shimizu successfully raised antibodies against the A $\beta$  peptide-KLH conjugate. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the

Art Unit: 1654

teachings. (In re Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); In re Bode 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

This is a provisional obviousness-type double patenting rejection.

### **Response to Arguments**

Applicants stated that they would consider submitting a Terminal disclaimer over the co-pending application.

Applicant's arguments filed 11/30/10 have been fully considered but they are not persuasive. Applicants have been contacted about the filing of a terminal disclaimer along with proposed amendments to the claims and no such amendments and TD have been filed in the application.

### **New grounds of Objections/Rejections**

#### **Claim Objections**

Claims 42 and 46 are objected to because of the following informalities: The aforementioned claims contain peptide sequences that require SEQ ID NOs. Appropriate correction is required.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SATYANARAYANA R. GUDIBANDE/  
Examiner, Art Unit 1654  
/Andrew D Kosar/  
Primary Examiner, Art Unit 1654